Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES *ex rel.* ADRIAN MEDINA, *Plaintiffs*, v. STRYKER ORTHOPAEDICS, *et al.*, *Defendants*.	Civil Action No. 16-2583 **OPINION**

John Michael Vazquez, U.S.D.J.

This is a False Claims Act ("FCA") case involving medical supplies that were billed to the Department of Veterans Affairs ("VA") and Department of Defense ("DOD"). Currently pending before the Court is a motion to dismiss filed by Defendants Stryker Orthopaedics and Stryker Corporation.[1] D.E. 36. Plaintiff Adrian Medina ("Plaintiff" or "Relator") filed a brief in opposition, D.E. 40, to which Defendants replied, D.E. 41.[2] The Court reviewed the submissions made in support and in opposition to the motion and considered the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons that follow, Defendants' motion is **GRANTED in part** and **DENIED in part**.

[1] Plaintiff collectively refers to both Defendants as a single entity in the FAC. *See* First Am. Compl. ("FAC") ¶ 11, D.E. 29. Defendants state that Stryker Orthopaedics is actually Howmedica Osteonics Corp. Defs. Br. at 1. Defendants, however, do not treat the entities separately for purposes of this motion. Thus, the Court does the same, referring to the entities collectively as "Defendants" or "Stryker".

[2] Defendants' brief in support of their motion (D.E. 36-1) will be referred to as "Defs. Br."; Plaintiff's brief in opposition (D.E. 40) will be referred to as "Plf. Opp."; and Defendants' reply brief (D.E. 41) will be referred to as "Defs. Reply".

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Background[3]

Relator Adrian Medina was an analyst at Stryker from March 2013 until he resigned in May 2016.[4] First Am. Compl. ("FAC") ¶ 16, D.E. 29. Stryker is a "global corporation" that supplies various products, including "implantable devices," that are primarily used in the medical field. *Id.* ¶ 11. During his employment, Relator allegedly learned that Stryker was violating the Trade Agreements Act ("TAA"), 19 U.S.C. § 2501 *et seq.*, through contracts with the DOD and VA. Generally, the TAA requires that the United States only purchase products from countries that are party to a trade agreement with the United States. Relator contends that thousands of Stryker products purchased by the DOD and VA are improperly designated as products of countries that are TAA compliant.[5]

Plaintiff alleges that Stryker "may have been aware" of the country of origin ("COO") issue as early as 2013. *Id.* ¶ 18. Plaintiff continues that by no later than the second quarter of 2015, emails and meeting notes indicate that Stryker employees knew that thousands of products that Stryker represented were from TAA compliant countries were actually manufactured in China and Malaysia. *Id.* ¶ 20. Plaintiff alleges that these products were manufactured in Malaysia and China

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[3] The factual background is taken from the FAC. D.E. 29. When reviewing a motion to dismiss, a court accepts as true all well-pleaded facts in a complaint. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

[4] The FAC is not a model of clarity, so the Court briefly recounts Relator's allegations, as best as can be discerned, and discusses specific allegations in the analysis section below.

[5] Plaintiff contends that the mis-designated products were manufactured in China, Malaysia, India, Taiwan, Indonesia and "possibly Thailand." FAC ¶¶ 50, 63. Taiwan is a designated country under the TAA. 48 C.F.R. § 52.225-5(a). Thus, to the extent that products were manufactured in Taiwan, these items should not be included in this matter and the Court disregards references to Taiwan in the FAC. In addition, although Plaintiff mentions India, Indonesia, and Thailand in a single paragraph of the FAC, Plaintiff's specific allegations focus on China and Malaysia.

then shipped to Stryker facilities in TAA compliant countries, such as Germany, Ireland, and the United States. Stryker then used these new addresses for COO purposes. *Id.* ¶¶ 35-36. In addition, although the TAA permits the government to provide exceptions on various grounds, Plaintiff alleges that the government had not done so. *Id.* ¶ 33.

Plaintiff also indicates that in 2015, Plaintiff's team learned that DOD and VA contracts were going to be administered by a different acquisition center. This change required Stryker to resubmit "eCat"[6] ("ECAT") proposals, which included COO certifications. *Id.* ¶ 55. While preparing to resubmit the ECAT proposals, Glenn Dumont, a Stryker employee, "advised higher ups" that products manufactured in China did not have proper COO certifications. *Id.* ¶ 56. Plaintiff was then directed to quantify the improperly designated products. As a result, Plaintiff created a spreadsheet with thousands of products that violated the TAA. *Id.* ¶¶ 61-66. Plaintiff provided the spreadsheet to his supervisor. *Id.* ¶ 67. However, it does not appear that Stryker changed COO designations for any products when it resubmitted the ECAT proposals. *Id.* ¶ 76.

In addition, Plaintiff pleads that Stryker created a program to ascertain the COOs for more than 1600 products in 2016 and, through this initiative, created another spreadsheet of products that did not comply with the TAA. *Id.* ¶¶ 75, 79. This spreadsheet appears to the Court to be

[6] "ECAT is an internet solution that uses the latest technology for ordering, distribution, and payment, providing Department of Defense and other Federal agencies access to multiple manufacturers' and distributors' commercial catalogs at discounted prices." Electronic Catalog (ECAT), DLA Troop Support Medical, DEFENSE LOGISTICS AGENCY, https://www.dla.mil/TroopSupport/Medical/ECAT/. While not clearly set forth in the FAC, it appears that Stryker and other government suppliers list products on ECAT and that purchasing contracts and payment for the DOD are also facilitated through ECAT. Defendants state that "the VA maintains National Standardization Contracts, which operate in a similar manner as DLA ECAT contracts." Defs. Br. at 5 n.3; *see also* About the National Acquisition Center (NAC), U.S. DEPT. OF VETERANS AFFAIRS, https://www.va.gov/opal/about/nac.asp.

separate from the spreadsheet created by Plaintiff. Moreover, it is not clear if this initiative was prompted by Dumot's internal notice or if it was spurred by a separate reason.

Finally, Plaintiff alleges that at some undisclosed time, Stryker attempted to obtain a TAA exception for undisclosed products. *Id.* ¶¶ 52-53. Plaintiff makes passing reference to numerous exceptions under the TAA throughout the FAC but fails to specifically allege the basis for any exception that Stryker sought. However, after Plaintiff filed the initial Complaint in this matter, Stryker obtained an "exception" from either a DOD or VA contracting officer. *Id.* ¶ 83. Again, Plaintiff does not explain what exception was granted or which products were excepted.

B. Procedural Background

On May 6, 2016, Plaintiff filed his *qui tam* Complaint alleging that Defendants submitted false claims to the Government in violation of the FCA, 31 U.S.C. § 3729 *et. seq.* D.E. 1. As required by the FCA, Plaintiff's Complaint was filed under seal and the Government was given an opportunity to review the allegations. D.E. 3. Ultimately, the Government decided not to intervene. D.E. 15. The Complaint was unsealed, D.E. 17, and served on Defendants, D.E. 22, 23. Plaintiff then filed the FAC on January 29, 2021. In the FAC, Plaintiff asserts claims alleging a violation of the FCA (Count One); conspiracy to violate the FCA (Count Two); and three common law claims (Counts Three through Five).[7] D.E. 29. In response, Defendants filed the instant motion, seeking to dismiss the FAC in its entirety. D.E. 36.

[7] In his opposition brief, Plaintiff contends that he asserts a FCA fraudulent inducement claim. Plf. Opp. at 13-15. A FCA fraudulent inducement claims permits a relator to bring a claim based on a fraudulent statement to the government, "even in the absence of evidence that the claims were fraudulent in themselves." *U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014). The FCA does not include a fraudulent inducement claim and Plaintiff cannot amend his pleading through a brief. *Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.") (quoting *Car Carriers, Inc. v. Ford Motor Co.,* 745 F.2d 1101, 1107 (7th

II. LEGAL STANDARD

Defendants seek to dismiss the FAC pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). To decide a Rule 12(b)(1) motion, based on lack of subject-matter jurisdiction, a court must first determine whether the party presents a facial or factual attack against a complaint. A facial attack contests "subject matter jurisdiction without disputing the facts alleged in the complaint, and it requires the court to 'consider the allegations of the complaint as true.'" *Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016) (quoting *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006)). A factual attack challenges "the factual allegations underlying the complaint's assertion of jurisdiction, either through the filing of an answer or 'otherwise presenting competing facts.'" *Davis*, 824 F.3d at 346 (quoting *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014)). Here, in seeking dismissal for lack of subject-matter jurisdiction, the parties rely solely on Plaintiff's allegations in the FAC. Accordingly, Defendants present a facial attack. As a result, like a Rule 12(b)(6) motion to dismiss, "the Court must consider the allegations of the complaint as true." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

For a complaint to survive dismissal under Rule 12(b)(6), for failure to state a claim upon relief may be granted, it must contain sufficient factual matter to state a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Further, a plaintiff must "allege sufficient facts to raise a reasonable expectation that

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Cir.1984)). Consequently, the Court disregards Plaintiff's argument about a FCA fraudulent inducement claim.

discovery will uncover proof of her claims." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 789 (3d Cir. 2016). In evaluating the sufficiency of a complaint, district courts must separate the factual and legal elements. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-211 (3d Cir. 2009). Restatements of the elements of a claim are legal conclusions, and therefore, not entitled to a presumption of truth. *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 224 (3d Cir. 2011). The Court, however, "must accept all of the complaint's well-pleaded facts as true." *Fowler*, 578 F.3d at 210.

Moreover, because the FCA is an anti-fraud statute, FCA claims are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). Rule 9(b) provides that a party alleging fraud "must state with particularity the circumstances constituting fraud or mistake," but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Accordingly, Rule 9(b) requires that a plaintiff allege "all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.'" *U.S. ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019) (quoting *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016)). With respect to a FCA claim, a plaintiff must "allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

III. ANALYSIS

A. Count One – Violation of the FCA

"The False Claims Act was adopted in 1863 and signed into law by President Abraham Lincoln in order to combat rampant fraud in Civil War defense contracts." *U.S. ex rel. Spay v. CVS Caremark Corp.,* 875 F.3d 746, 753 (3d Cir. 2017) (quoting *Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*, 575 U.S. 650, 652 (2015)). The FCA's primary purpose "is to indemnify the government - through its restitutionary penalty provisions – against losses caused by a defendant's fraud." *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001) (citing *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 549, 551-52 (1943)). The FCA has since evolved but continues to penalize persons who knowingly submit fraudulent claims to the Government. *See U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.,* 944 F.2d 1149, 1152 (3d Cir. 1991).

A private party, called a relator, may bring a *qui tam*[8] action on behalf of the Government alleging a violation of the FCA. 31 U.S.C. § 3730(b). In its current form, the FCA "imposes civil penalties and treble damages on defendants who submit false or fraudulent claims to the government. Individual relators can receive between 15% and 30% of the recovered amount. *Spay*, 875 F.3d at 753.

Section 3729(a)(1) creates liability for, among other things, "any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material

[8] The term *qui tam* action comes from the Latin phrase, *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, meaning "who as well for the king as for himself sues in this matter." Black's Law Dictionary (10th ed. 2014). A *qui tam* action is an "action brought under a statute that allows a private person to sue for a penalty, part of which the government or some specified public institution will receive." *Id*.

to a false or fraudulent claim."[9] 31 U.S.C. § 3729(a)(1). To establish a prima facie violation of the FCA, a plaintiff-relator "must prove that (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Wilkins v. United Health Grp., Inc.,* 659 F.3d 295, 305 (3d Cir. 2011)). Ultimately, a FCA claim includes four elements: "falsity, causation, knowledge, and materiality." *U.S. ex rel. Petratos v. Genentech Inc. ("Petratos II"),* 855 F.3d 481, 487 (3d Cir. 2017) (citation omitted).

1. False Claim

The definition of claim is statutorily defined as "any request or demand . . . for money or property" that is presented to an "officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2). The FCA does not define false or fraudulent. The Third Circuit, however, has explained that "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment as set by the government." *U.S. ex rel. Druding v. Care Alts.*, 952 F.3d 89, 97 (3d Cir. 2020). The Circuit further explained that in a FCA case, false claims fall into two categories: factually false claims and legally false claims. *Id.* at 96. "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government[.]" *Wilkins*, 659 F.3d at 305. By comparison, "a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statue or regulation the compliance with which is a condition for Government

[9] In May 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), "which amended the FCA and re-designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B)." *Wilkins*, 659 F.3d at 303. The effective date of the FERA amendment was made retroactive to any claims pending as of June 7, 2008. *Id.* at 303-04. Plaintiff's allegations here involve conduct that, at the earliest, began in 2013. *See* FAC ¶ 18. As a result, the current, amended version of the FCA applies to Plaintiff's claims.

payment." *Druding*, 952 F.3d at 96. The false claims at issue here are legally false claims because Plaintiff contends that Defendants misrepresented that Stryker's products complied with the TAA.

Legally false claims are further divided into two types: express and implied certifications. *Wilkins*, 659 F.3d at 305. An express false certification occurs when an entity certifies that it is in compliance with the legal requirements that are "prerequisites to Government payment in connection with the claim for payment of federal funds." *Id.* (citation omitted). Implied false certification liability arises when an entity makes a claim to the Government for payment while implying, but not expressly certifying, that it is in compliance with the legal preconditions for payment. *Id.* (citing *Mikes*, 274 F.3d at 699). In this instance, Plaintiff alleges that government contractors are required to certify that products they are selling to the government comply with the TAA. FAC ¶¶ 27, 29; *see also* 48 C.F.R. § 52.225-6 (generally requiring an offeror to certify that each end product is "U.S. made or designated country end product"). Accordingly, this case involves express certifications.

Turning to the TAA, it generally requires that the United States purchase products from designated countries.[10] 19 U.S.C. § 2501 *et seq.* If a product is not manufactured in the United States, it must be an "eligible product," which means that the product or service originates from a country or instrumentality with which the United States has a trade agreement.[11] 19 U.S.C. § 2518(4). The President, however, can make (and take away) waivers for certain countries, subject

[10] The TAA applies to government contracts above specified monetary thresholds. *See* 48 C.F.R. § 25.402. No party disputes that the TAA and its implementing regulations, the Federal Acquisition Regulations ("FAR") applies to this dispute based on the monetary amount involved in Stryker's contracts with the VA and DOD.

[11] Relatedly, the Buy American Act generally provides that the United States shall only acquire products for the public use that are manufactured, mined, or produced in the United States, provided that the cost of doing so would not be unreasonable, of unsatisfactory quality or quantity, or would otherwise be inconsistent with the public interest. 41 U.S.C. § 8302. Thus, goods and services acquired by the United States must comply with the Buy American Act and/or the TAA.

to specific criteria. 19 U.S.C. § 2511. Finally, the TAA applies to "end products," although there is an exception if a product is "substantially transformed" into a new and different article in a country other than where it originated. 48 C.F.R. §§ 25.1101; 52.225-5(a).

Here, Plaintiff alleges that Stryker certified that products it supplied to the VA and DOD were manufactured in TAA designated countries and the United States, when they were actually manufactured in China and Malaysia, non-TAA designated countries. Specifically, Plaintiff pleads that by 2016, Defendants knew that "thousands of products" were improperly certified as TAA compliant. FAC ¶ 25. Plaintiff alleges that products were manufactured in Malaysia and China, shipped to other Stryker facilities in TAA compliant countries, and then "relabeled" with the new location as the COO. *Id.* ¶¶ 35-36. Plaintiff provides specific examples of this practice: a forged hip implant that was allegedly manufactured in China, shipped to another Stryker facility and then to New Jersey, and designated as "United States" for COO purposes, *id.* ¶¶ 36, 45-47; and a headless fluted pin, which was also manufactured in China, shipped to New Jersey, and designated as a product of the United States for COO purposes, *id.* ¶ 54.

Defendants maintain that Plaintiff fails to sufficiently plead that the identified items were end products. Defs. Br. at 20-25. An end product is defined in the FAR as "those articles, materials, and supplies to be acquired under the contract for public use." 48 C.F.R. §§ 25.1101; 52.225-5(a). The term is further defined as an item that is "wholly the growth, product, or manufacture" of a designated country or "[i]n the case of an article that consists in whole or in part of materials from another country, has been substantially transformed" in a designated country. *See id.* § 52.225-5(a)(1)(i). Here, Defendants contend that neither the hip implant nor the pin are end products because they are "component parts of an orthopedic implant 'Procedural Package.'" Defs. Br. at 24.

Plaintiff does not plead that the headless fluted pin or hip implant were part of a larger package. Defendants, however, argue that the Court can consider this fact in deciding this motion through various ECAT contracts and proposals that are referenced in the FAC. *Id.* at 5 n.2. In deciding a Rule 12(b)(6) motion, a court ordinarily considers only the factual allegations in the pleading, exhibits attached to the complaint, and matters of public record. A court may also rely on "a document *integral to or explicitly relied* upon in the complaint." *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002) (emphasis in original) (citation omitted). A document is integral if a "claim would not exist but-for the existence of the document." *Dix v. Total Petrochems. USA, Inc.*, No. 10-3196, 2011 WL 2474215, at *1 (D.N.J. June 20, 2011). Here, Plaintiff alleges that the non-TAA compliant products were listed on ECAT and that Stryker's ECAT proposals required COO certifications. *See, e.g.*, FAC ¶¶ 54-55. As discussed, while not explicitly stated in the FAC, it appears that the false claims were submitted through ECAT. *Id.* ¶ 56. As a result, the Court considers the ECAT contracts and proposals (*see* Cert. of Bruce A. Levy ("Levy Cert."), Exs. A, I, J.) in deciding this motion, as they are both integral to and expressly relied upon in the FAC.[12]

Defendants contend that the ECAT contracts demonstrate that the two specifically identified products (the hip implant and headless fluted pin) were purchased as a component of a

[12] Defendants also seek to dismiss the FAC because Plaintiff fails to identify the procurement contracts at issue. Defs. Br. at 24. Plaintiff is not required to specifically identify each falsely submitted claim, or even provide a specific example contract. *See Bookwalter*, 946 F.3d at 176 ("The falsity here comes not from a particular misrepresentation, but from a set of circumstances that, if true, makes a whole set of claims at least prima facie false."). More importantly, Defendants themselves "identified (at least) most of the contracts and Justifications & Approvals" at issue, Defs. Reply at 7, and argue that the Court can consider these documents in deciding other portions of the motion to dismiss, Defs. Br. at 5 n.2. Because the Court will consider the ECAT contracts and proposals to decide this motion and because Defendants have identified the contracts, the Court declines to dismiss the matter for failure to adequately identify the agreements.

surgical kit rather than specific items. Defendants continue, therefore, that the end products are the surgical kit, not the individual pieces within the kit. Because Plaintiff fails to plead that any mis-designated products were end products under the TAA, Defendants maintain that Plaintiff fails to allege any violation of the TAA. Defs. Br. at 21-25. The Court disagrees. First, Plaintiff was an employee at Stryker from March 2013 through May 2016. FAC ¶ 16. Plaintiff alleges that Defendants may have been aware of the COO problem as early as 2013 and focuses on emails and events that occurred in the fourth quarter of 2015 and first quarter of 2016. *Id.* ¶¶ 18-26. Two of the contracts, however, occurred after this time and post-date Plaintiff's employment with Stryker. *See* Levy Cert., Ex. I (VA contract dated December 1, 2016); Ex. J (DLA contract awarded to Stryker on February 6, 2017). Moreover, although all three contracts mention "procedural packages," the 2013 and 2016 contracts include a list of discounts for specific items. *See* Levy Cert., Ex. A and I. Thus, viewing these contracts in a light most favorable to Relator, the Court can plausibly infer that although specific groups of items were purchased together, specific items were sold *a la carte*. The fact that Defendants gave discounts for specific items undermines Defendants' argument that Stryker only contracted to sell the items as a package.

Defendants also argue that there is not a straightforward answer to whether an item constitutes an end product under the TAA. To that end, Defendants maintain that "the purpose of the procurement as demonstrated by the entire bid package must be reviewed." Defs. Br. at 21 (quoting *Textron, Inc., Bell Helicopter Div. v. Adams*, 493 F. Supp. 824, 834 (D.D.C. 1980)). But this does not change the Court's conclusion at this stage. If anything, Defendants' argument bolsters the Court's conclusion. At best, the ECAT contracts are unclear as to whether the specific items identified by Plaintiff were purchased individually or if they were solely included as part of a system that was purchased as a whole. In addition, Defendants' argument highlights the fact that

whether a product is an end product is a fact sensitive determination. As a result, the Court will not (and cannot at this stage) make a factual determination based solely on the pleadings and documents integral to the pleadings.[13]

In addition, outside of the two examples, Plaintiff alleges that thousands of Stryker products had incorrect COO designations. *See, e.g.*, FAC ¶ 63. Defendants counter that the FAC only has "broad and sweeping allegations" that lack precision. Defs. Br. at 24. Again, the Court disagrees. Plaintiff contends that he assembled a spreadsheet identifying thousands of mislabeled products by item number (including the two examples addressed above) and that he provided this spreadsheet to his supervisor. FAC ¶¶ 62-67. Although Plaintiff does not list every item on the spreadsheet, he sufficiently describes the spreadsheet, what it contained, and critically, Defendants' alleged scheme of mis-designating items. Notably, Plaintiff pleads that a Stryker employee received the spreadsheet, and that email and meeting notes indicate the numerous Stryker employees were aware of the allegations of misconduct at the time.[14] *Id.* ¶ 67. Thus, Defendants have sufficient notice of the specific end products that were allegedly mis-labeled and the overarching alleged scheme.[15]

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[13] Because Plaintiff plausibly pleads that the hip implant and headless fluted pin were end products, the Court does not address Defendants' argument as to substantial transformation. *See* Defs. Br. at 22-24.

[14] As discussed, Plaintiff refers to two spreadsheets in the FAC: the one he created, *see* FAC ¶¶ 62-67, and another created by Stryker, *see* FAC ¶¶ 79-82. Defendants raise several legal challenges to the spreadsheet that was created by Stryker, including that Plaintiff did not include a copy of the spreadsheet as an exhibit to the FAC and that it is protected by the attorney client privilege and work-product doctrine. Defs. Reply at 6-7. Because this second spreadsheet is not material to the Court's analysis, the Court does not reach these arguments.

[15] Defendants also argue that they received exceptions "for many of the products at issue in this case." Defs. Reply at 8-9. Defendants implicitly concede that they did not obtain exceptions for every product. Accordingly, this argument cannot justify dismissing the FAC as a whole.

In sum, Plaintiff plausibly pleads that Defendants submitted false claims.

2. Scienter

Next, Defendants argue that Plaintiff fails to plausibly allege that Stryker knowingly submitted false claims prior to 2015. Defs. Br. at 27-29. Under the FCA, "knowing" or "knowingly" means "that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information[.]" 31 U.S.C. § 3729(b)(1). This scienter requirement does not require an intent to defraud, but an innocent mistake or simple negligence is insufficient. *U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.,* 495 F.3d 103, 109 (3d Cir. 2007) (citations omitted). Plaintiff alleges that Stryker "may have been aware" of the COO issue as early as 2013. FAC ¶ 18. Plaintiff further alleges that unidentified salespeople identified the problem in 2014. *Id.* ¶ 38. Plaintiff continues that by no later than the second quarter of 2015, emails and meeting notes demonstrate that products represented as TAA compliant were really manufactured in China and Malaysia. *Id.* ¶ 20. Moreover, Plaintiff pleads that specific employees met and discussed the alleged problem in September 2015. *Id.* ¶ 21. These allegations more than sufficiently allege that, at least by September 2015, Stryker had actual knowledge of the allege misconduct. Consequently, Plaintiff sufficiently pleads scienter.

Stryker also argues that its "posthumous exception . . . renders implausible any claim that Stryker acted with the requisite knowledge of falsity." Defs. Br. at 29. Plaintiff pleads that Stryker received an "exception" from "either a DOD or VA contracting officer." FAC ¶ 83. Defendants explain that because Stryker obtained an exception, this demonstrates that whether the products were end products under the TAA was a disputed legal question, such that Stryker could not have acted with the requisite scienter when it certified that the products were TAA compliant. Defs.

Reply at 12. But the FAC provides no details about the exception, including what products it covered or why it was granted. Plaintiff also pleads that the exception "most certainly does not cover all of the thousands of products" that violated the TAA. FAC ¶ 52. Critically, the FAC does not suggest that the exception was granted because Stryker was uncertain whether certain products were end products.[16] Accordingly, the limited information about Stryker's *ex post facto* exception does not negate Plaintiff's allegations demonstrating Stryker's knowledge when it submitted any TAA certifications.

3. Materiality

Next, Defendants argue that Relator fails to plead that the alleged false claims were material to the government's decision to approve or pay for the products at issue. Defs. Br. at 29-35. Plaintiff counters that he does not need to establish that Defendants' conduct was material to the Government's decision to pay here. Rather, a plaintiff-relator only needs to demonstrate that the alleged wrongful conduct had a natural tendency to influence payment. Plf. Opp. at 19-21.

The Supreme Court has explained that materiality is an "essential element" for a FCA claim, and the standard for establishing materiality "is demanding." *United Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016). Moreover, "materiality 'looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 193 (quoting 26

[16] Plaintiff makes passing reference to the sole source and substantial transformation exceptions when discussing Stryker's attempt to obtain an exception. FAC ¶ 53. In his opposition brief, Plaintiff suggests that the exception was granted because the end products were the procedural package rather than each individual product. *See* Plf. Opp. at 13 (stating that Stryker obtained an exception related to packaging the products in trays). The Court also notes that Stryker appears to argue that the legal dispute involved whether end products were a single component. Defs. Reply at 12. The only reference to a disputed legal issue, however, is the allegation that Stryker retained a law firm to provide advice on the "substantial transformation" exception. FAC ¶ 18. Thus, viewing the FAC in a light most favorable to Plaintiff, it appears that Stryker at least attempted to obtain an exception on known grounds rather than based on legal uncertainty. And the parties' briefs bolster this conclusion.

R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)) (internal brackets omitted); *see also* 31 U.S.C. § 3729(b)(4) ("[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."). The Supreme Court went on to discuss factors that are relevant, although not necessarily dispositive, to a court's materiality determination under the FCA. *Id.* at 194-95. Defendants focus on the following discussion:

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id.

Among other things, Defendants contend that Plaintiff fails to plead that the Government consistently refuses to pay in similar cases or that, in this case, Stryker's alleged non-compliance affected the government's decision to pay. Defs. Br. at 33. Defendants continue that the fact that the Government has not canceled any contracts and granted a posthumous exception demonstrates that Stryker's failure to correctly designate the country of origin, as required by the TAA, was not material. *Id.* at 33-34. Giving Plaintiff the benefit of every reasonable inference, the fact that Stryker received an exception after the fact is a change in position on the government's behalf. At

the motion to dismiss stage, the Court views this as a change in position that, broadly speaking, supports an inference of materiality.[17]

4. Causation

Finally, Defendants maintain that Relator does not adequately plead causation. "[O]rdinary causation principles from negligence law" are applicable to FCA claims. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 245 (3d Cir. 2004); *see also Petratos II*, 855 F.3d at 491 (stating that "but for" causation is not enough to satisfy the causation requirement under the FCA). Defendants again rely on the fact that Stryker received an exception in arguing that Plaintiff fails to sufficiently plead causation. Defs. Br. at 36. As explained, it appears that after learning that Stryker was mis-designating the country of origin on certain products, the government granted Stryker an exception under the TAA to ensure that the Stryker contracts did not violate the TAA. This is sufficient at the motion to dismiss stage to plead causation, as Plaintiff pleads that Stryker's improper country of origin designations proximately caused the government to pay false claims.

In sum, Relator sufficiently pleads a FCA claim based on his allegations that Stryker was not properly designating the country of origin for certain of its end products that were purchased by the VA and DOD, in violation of the TAA. Defendants' motion, therefore, is denied with respect to the Count One.[18]

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[17] Defendants also contend that the U.S. Attorney's Office decision to not intervene in this case makes Plaintiff's allegations of materiality implausible. *Id.* at 33-34. But "intervention decisions are, at best, of minimal relevance." *U.S. ex rel. Int'l Bhd. of Elec. Workers Local Union No. 98 v. Farfield Co.*, 5 F.4th 315, 346 (3d Cir. 2021). The Court, therefore, gives little weight to the U.S. Attorney's Office's decision not to intervene in deciding this motion.

[18] In the FAC, Relator pleads that Stryker failed to provide the Food and Drug Administration ("FDA") and U.S. Customs and Border Protection with accurate information. FAC ¶¶ 8, 35-37, 73. Relator does not, however, plead which FDA or customs rules Stryker allegedly violated. Accordingly, to the extent that Relator intends to assert FCA claims based on these alleged violations, they are dismissed as implausibly pled.

B. Count Two – FCA Conspiracy

In Count Two, Plaintiff alleges that Defendants conspired with each other to defraud the United States. FAC, Second Count ¶ 2. To state a claim for conspiracy to violate the FCA, a plaintiff must allege "(1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy." *U.S. ex rel. Greenfield v. Medco Health Sys., Inc.*, No. 12-522, 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014). "[T]he essence" of a FCA conspiracy claim "is an agreement between two or more persons to commit fraud." *Id.*

Here, while Plaintiff asserts claims against two Defendants, he treats them as a single entity in the FAC. *See* FAC ¶ 11 (explaining that Plaintiff collectively refers to both Defendants as Stryker). Thus, Plaintiff fails to adequately plead that there was an agreement between the two entities. Further, although Plaintiff alleges that different Stryker employees "were aware" of the alleged FCA violation, *see, e.g.*, *id.* ¶ 70, Plaintiff fails to plead plausible facts establishing that there was any agreement between or among these employees to submit false claims. Moreover, under the intracorporate conspiracy doctrine, "an entity cannot conspire with one who acts as its agents."[19] *U.S. v. Wavefront, LLC*, No. 20-5094, 2021 WL 37539, at *10 (D.N.J. Jan. 5, 2021)

Relator also appears to base his FCA claim on 31 U.S.C. § 3729(a)(1)(E). Briefly, subsection (a)(1)(E) provides that a person may be liable if he "is authorized to make or deliver a document certifying receipt of property used, or to be used by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true." 31 U.S.C. § 3729. The FAC is devoid of any allegations that support such a claim. Thus, to the extent that Plaintiff meant to assert a FCA claim based on this subsection, it too is dismissed as implausibly pled.

[19] Plaintiff does not address any of Defendants' arguments for dismissal of the conspiracy claim, including whether the Court can apply the intracorporate conspiracy doctrine. The Court notes, however, that there is a divide as to whether the intracorporate conspiracy doctrine applies to FCA conspiracies. *See Wavefront, LLC*, 2021 WL 37539, at *11. The Third Circuit has not addressed the issue. This Court finds the cases applying the intracorporate conspiracy doctrine to FCA claims persuasive. *See id.* (explaining that doctrine precluded conspiracy claim alleging a FCA conspiracy between entity and its employees); *United States ex rel. Laporte v. Premier Educ. Grp.,*

(quoting *Gen. Refractories Co. v. Fireman's Fund Ins. Co.*, 337 F.3d 297, 313-14 (3d Cir. 2003)). Thus, Plaintiff's conspiracy claim fails for this reason as well. Accordingly, Plaintiff fails to state a FCA conspiracy claim and Count Two is dismissed.

C. Counts Three to Five – Common Law Claims

Finally, in Counts Three through Five, Plaintiff asserts common law claims on behalf of the United States. *See, e.g.*, FAC, Fourth Count ¶¶ 1-4 (alleging that Defendants have been unjustly enriched at the United States' expense). Plaintiff does not allege that he was personally harmed by Defendants' allegedly wrongful conduct. Defendants contend that Plaintiff's common law claims must be dismissed because Plaintiff lacks standing to assert these on behalf of the United States. Defs. Br. at 39. Plaintiff fails to address this argument.

To establish Article III standing, a plaintiff "must demonstrate '(1) an injury-in-fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision."' *Finkelman v. Nat'l Football League*, 810 F.3d 187, 193 (3d Cir. 2016) (quoting *Neale v. Volvo Cars of N. Am., LLC,* 794 F.3d 353, 358–59 (3d Cir. 2015) (internal quotation marks omitted and punctuation modified)). An injury-in-fact requires a plaintiff to show that he suffered "an invasion of a legally protected interest" that is "concrete and particularized[.]" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

Section 3730(b) permits a person to bring a civil action, in the name of the government, that alleges a violation of Section 3729. 31 U.S.C. § 3730(b). Section 3729 imposes liability for certain acts involving false or fraudulent claims for payment by the Government. 31 U.S.C. §

L.P., No. 11-3523, 2016 WL 2747195, at *19 (D.N.J. May 11, 2016) ("These facts do not allow the Court to infer an agreement between the two because Relators have effectively pled that [the two entities] are the same entity for all intents and purposes."); *Greenfield*, 2014 WL 4798637, at *11-12 (concluding that doctrine barred allegations that parent and subsidiaries conspired to violate the FCA).

3729(a). Thus, "[w]hile the FCA gives a relator the right to bring an action for a violation of the FCA, the FCA 'does not give relators the right to assert common law claims on behalf of the United States.'" *U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 451 (S.D.N.Y. 2001) (quoting *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 149 (D. Mass. 2000)). Consequently, because Plaintiff cannot assert these claims on behalf of the government and he fails to establish that he personally suffered any injury, Plaintiff lacks standing to assert the common law claims. Counts Three through Five, therefore, are dismissed.

IV. CONLCUSION

For the reasons stated above, Defendants' motion to dismiss (D.E. 36) is **GRANTED in part** and **DENIED in part**. Defendants' motion is **GRANTED** as to Counts Two through Five of the First Amended Complaint. Count Two is dismissed without prejudice, and Plaintiff is granted leave to file an amended pleading that remedies the identified deficiencies as to Count Two. Plaintiff's amended pleading must be filed within thirty (30) days of the date of this Order or Count Two will be dismissed with prejudice. Counts Three through Five are also dismissed without prejudice but Plaintiff is not granted leave to file an amended pleading as to these Counts because he lacks standing. Defendants' motion is otherwise **DENIED**. An appropriate Order accompanies this Opinion.

Dated: February 22, 2022

John Michael Vazquez, U.S.D.J.